UNITED STATES ENVIRONMENTAL PROTECTION AGENCY CHARTER

HUMAN STUDIES REVIEW BOARD

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1. Committee's Official Designation (Title):

Human Studies Review Board

2. Authority:

This charter establishes the Human Studies Review Board (HSRB) in accordance with the provisions of the Federal Advisory Committee Act (FACA), 5 U.S.C. App.2 § 9 (c). HSRB is in the public interest and supports EPA in performing its duties and responsibilities.

3. Objectives and Scope of Activities:

HSRB will provide advice, information, and recommendations on issues related to scientific and ethical aspects of human subjects research.

The major objectives are to provide advice and recommendations on:

a. Research Proposals and Protocols;

b. Reports of completed research with human subjects; and

c. How to strengthen EPA's programs for protection of human subjects of research.

4. Description of Committees Duties:

The duties of the HSRB are solely advisory in nature.

5. Official(s) to Whom the Committee Reports:

HSRB will report to the EPA Administrator through EPA's Science Advisor (OSA).

6. Agency Responsible for Providing the Necessary Support:

EPA will be responsible for financial and administrative support. Within EPA, this support will be provided by the Office of the Science Advisor.

7. Estimated Annual Operating Costs and Person Years:

The estimated annual operating cost of HSRB is $750,000 which includes 2.0 person-years of support.

8. Estimated Number and Frequency of Meetings:

The Committee expects to meet approximately four (4) times a year. Meetings may occur approximately once every three (3) months or as needed and approved by the Designated Federal Officer (DFO). EPA may pay travel and per diem expenses when determined necessary and appropriate. A full-time or permanent part-time employee of EPA will be appointed as the DFO. The DFO or a designee will be present at all meetings and each meeting will be conducted in accordance with an agenda approved in advance by the DFO. The DFO is authorized to adjourn any meeting when he or she determines it is in the public interest to do so.

As required by FACA, HSRB will hold open meetings unless the EPA Administrator determines that a meeting or a portion of a meeting may be closed to the public in accordance with subsection c of Section 522(b) of Title 5, United States Code. Interested persons may attend meetings, appear before the committee as time permits, and file comments with the HSRB.

9. Duration and Termination:

This charter will be in effect for two years from the date it is filed with Congress. After this two-year period, the charter may be renewed as authorized in accordance with Section 14 of FACA.

10. Member Composition:

The HSRB will be composed of approximately fifteen (15) members. Members will serve either as Special Government Employees or regular government employees. In selecting members, EPA will consider candidates from the environmental scientific / technical fields, human health care professionals, academia, industry, public and private research institutes or organizations, other governmental agencies, and other relevant interest areas. The HSRB membership will include experts in relevant scientific or technical disciplines such as bio-statistics, human toxicology, including pharmacokinetic and toxicokinetic studies, clinical trials, and toxicology of cholinesterase inhibitors and other classes of environmental substances; bio-ethics; and human health risk assessment.

11. Subgroups:

EPA, or HSRB with EPA's approval, may form HSRB subcommittees or workgroups for any purpose consistent with this charter. Members of HSRB subcommittees or workgroups will serve either as Special Government Employees or regular government employees. Such subcommittees or workgroups may not work independently of the chartered committee and must report their recommendations and advice to the HSRB for full deliberation and discussion. Subcommittees or workgroups have no authority to make decisions on behalf of the chartered committee nor can they report directly to the Agency.

January 20, 2006
Agency Approval Date

January 24, 2006
GSA Consultation Date

February 21, 2006
Date Filed with Congress